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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

13

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/848,271

Applicant(s)

RUBEN ET AL.

Examiner

Eileen B. O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24, 26 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 33-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 24, 26 and 33-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 11 .                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 24, 26 and 33-43 are pending in the instant application. Claims 1, 20, 21 and 23 have been canceled as requested by Applicant in Paper Number 12, filed Oct. 18, 2002.

### ***Election/Restrictions***

2. Applicant's election with traverse of the antigenic epitope consisting of amino acid residues 105-111 of SEQ ID NO: 2 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that as the members of the Markush group of the pending claim 42 are sufficiently few in number and closely related, as they are all fragments of a single amino acid sequence disclosed in SEQ ID NO: 2, a search may be made without a serious burden. This is found persuasive, and all of the claims and all of the antigenic epitopes will be searched and examined.

The requirement is still deemed proper and is therefore made FINAL.

Claim 24 is withdrawn as being drawn to a non-elected invention.

Claims 26 and 33-43 are currently under examination.

### ***Specification***

3. The disclosure is objected to because of the following informalities: The Brief Description of the Figures on pages 6-7 should be deleted from the specification since there are no figures in the application. This will **not** constitute new matter. Also, references to the figures elsewhere in the specification (for example, page 47, lines 1-2, 4, 6, 14, 24, 26, 28, and 30) should be deleted.

Appropriate correction is required.

***Claim Objections***

4. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 26 is objected to for depending upon a cancelled claim.

***Information Disclosure Statement***

5. The sequences disclosed in the IDS filed Oct. 18, 2002, Paper No. 11 (references BC-BO) and the IDS filed August 9, 2002, Paper No. 9 (references AI-AT) have been considered to the extent that was possible absent an explanation of relevance or a sequence alignment.

***Claim Rejections - 35 USC § 101 and § 112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 26 and 33-43 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claims 26 and 33-43 are directed to methods for detecting Sjogren's disease comprising contacting an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2 with a biological sample from a patient, and assaying for either binding of neutrokin- $\alpha$  to the isolated polypeptide, or for binding of an antibody to the isolated polypeptide. However, the claimed

Art Unit: 1646

methods do not have any specific and substantial utility, or a well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The instant specification teaches that the polypeptide having the amino acid sequence of SEQ ID NO: 2, identified as TR18, is a receptor that binds the ligands neutrokin- $\alpha$  and APRIL, and that these ligands are expressed primarily on cells of monocytic lineage (page 123, lines 16-28). The specification also teaches that the TR18 polypeptides may be used as a means of detecting and/or quantifying levels of neutrokin- $\alpha$  or APRIL in a biological sample, and so can be used diagnostically (paragraph bridging pages 73-74, and page 123, lines 16-28). The instant application asserts that immunodeficiencies and autoimmune diseases may be treated, prevented, diagnosed and/or prognosed with the TR18 polypeptides, and presents extensive lists of such diseases or disorders on pages 124-130, and that an individual having an autoimmune disease or disorder may express aberrantly high levels of neutrokin- $\alpha$  or APRIL when compared to an individual not having an autoimmune disease or disorder (page 128, lines 20-27). However, because the specification has not provided any evidence that neutrokin- $\alpha$  or APRIL are differentially expressed in Sjogren's disease (or any asserted disease listed), and presents an extensive list of diseases or disorders that may be diagnosed using the TR18 polypeptides, the method of detecting Sjogren's disease is not a specific or substantial utility. There is no nexus between differential expression of neutrokin- $\alpha$  or APRIL and Sjogren's disease. A stated belief that a correlation exists between the TR18 polypeptide, neutrokin- $\alpha$  or APRIL and the diseases or disorders presented in the specification, is not sufficient guidance to use the claimed polypeptides in the methods of detection; it merely defines a starting point for further research

Art Unit: 1646

and experimentation. The use of the TR18 polypeptides as a diagnostic or prognostic marker is conjectural and would not, on the basis of the disclosure, be considered useful by one of skill in the art.

The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed polypeptides. This further characterization, however, is part of the act of invention and until it has been undertaken the Applicant's claimed invention is incomplete.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 26 and 33-43 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the specification were enabling of using the polypeptide of SEQ ID NO: 2 to detect Sjogren's disease, enablement would not be found commensurate in scope with the claims. Claims 41-43 encompass a method of detecting Sjogren's disease comprising contacting an isolated polypeptide comprising an antigenic epitope of the amino acid sequence of SEQ ID NO: 2 with a biological sample. The specification defines an antigenic epitope on page 55 as containing a sequence of at least 4 amino acids, so that the

Art Unit: 1646

claims encompass a protein that may be completely different from the polypeptide of SEQ ID NO: 2 except for comprising 4 amino acids of the sequence of SEQ ID NO: 2, and the specification has not disclosed any polypeptide besides that of SEQ ID NO: 2. Therefore, even if the specification were enabling for detecting Sjogren's disease with the polypeptide of SEQ ID NO: 2, it would not be enabling for such a method with a polypeptide that comprises only 4 amino acids of SEQ ID NO: 2

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 and 33-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1 Claims 39-43 are indefinite because claims 39 and 41 recite the limitation "binds specifically", it is not clear what this term means. The rejection would be withdrawn if the word "specifically" was deleted from the claims.

8.2 Claims 26 and 33-43 are indefinite because claims 26, 33, 36, 39 and 41 are incomplete method claims, and are not written with the different methods steps clearly recited. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved.

Art Unit: 1646

9. The art considered pertinent to the present application is Laabi et al. Nucleic Acid Research, Vol. 22, No. 7, pages 1147-1154, 1994, which discloses BCMA protein, which is 100% identical to the TR18 protein of SEQ ID NO: 2 of the instant invention. This reference does not teach or suggest what is being claimed, but is cited as the protein used in the claimed methods.

***Conclusion***

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.


Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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